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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,377

10/20/2004

Victor V. Lobanenko

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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,377	LOBANENKOV ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,13,23 and 42-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,9,13,42 and 43 is/are allowed.
- 6) ☒ Claim(s) 23 and 44-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 2, 13, and 23 have been amended.
Claims 3-8, 10-12, 14-22, and 24-41 have been cancelled.
Claims 42-57 have been added.
2. Claims 1, 2, 9, 13, 23, and 42-57 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on August 6, 2007 was filed after the mailing date of the first action on the merits on April 5, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this Office Action.

Objections Withdrawn

4. The objections to the specification are withdrawn in view of applicant's amendments to the specification.
5. The objection to claim 23 is withdrawn in view of applicant's amendment to the claim.

Rejections Withdrawn

6. The rejection of claims 1, 2, 9, 13, and 23 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendments.
7. The rejection of claims 1, 9, 13, and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendment to the claims.
8. The rejection of claims 2 and 24 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment and cancellation of the claims.
9. The rejection of claim 13 under 35 U.S.C. 101, as being directed to non-statutory subject matter is withdrawn in view of applicant's amendment to the claim.

Rejections Maintained

10. The rejection of claim 23, and newly added claims 44-57 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed August 6, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the claimed method of diagnosing a cancer or a predisposition to a cancer in a mammal is enabled by the present specification, as evidenced by the specification itself, and by post-filing publications that

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further support the validity of the assertions made in the present application. In particular, the specification discloses that BORIS, which is normally a testes-specific gene, is expressed in a variety of cancer cell lines, including breast cancer cell lines (see Example 5 and Table 1). BORIS expression also has been detected in primary tumor samples (e.g., Wilms tumor samples and breast tumor samples), which correlated with BORIS expression in cancer cell lines (see specification at, e.g., paragraph [00121]). The correlation of BORIS gene expression with cancer in cancer patients has been further demonstrated by Risinger, et al. and D'Arcy, et al. Risinger et al. discloses a high incidence of BORIS gene expression in uterine/endometrial cancers. D'Arcy et al. discloses that BORIS is expressed at high levels in leukocytes obtained from whole blood of breast cancer patients (Abstract). These results support the assertions of the present application that BORIS expression can be used as a clinical cancer marker in various cancers, and that the detection of BORIS can be facilitated using blood or tissue (somatic) samples (see response pages 9-10). In response to this argument, the specification and supporting references detected BORIS in patients or cell lines which were already cancerous, not prior to the formation of a cancer. Thus, the claims are enabled for detecting or diagnosing a cancer but not a predisposition to a cancer. A predisposition, when given the broadest reasonable interpretation can be defined as predicting that someone will be diagnosed with cancer at some future date. The specification and post-filing date references do not support a predisposition to a cancer.

Thus, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

Conclusion

11. Claims 1, 2, 9, 13, 42, and 43 are in condition for allowance.

Claims 23 and 44-57 are rejection.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

September 18, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER